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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,776	06/01/2006	Yoshikazu Morita	8062-1037	5526

466 7590 10/12/2007

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	**PAPER NUMBER**
1657	
MAIL DATE	**DELIVERY MODE**
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,776	MORITA ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *2-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-13* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claim 1) and species plasminogen in the reply filed on 07/30/2007 is acknowledged. The traversal is on the ground(s) that the lack of unity determination was improper and that the groups and species share the special technical feature of promoting osteogenesis and/or inhibiting bone resorption. This is not found persuasive because lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A +X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims (MPEP 1850). The inventions of Groups I-VII lack subject matter common to all the claims and therefore lack unity *a priori*. However, the Groups also lack unity *a posteriori* as demonstrated by the International Search Authority which discloses that the different inventions are known in different references (JP 03-099022A, JP 05-132426A, WO 2002/05836A2, JP 10-505592A). The species claimed by Applicant also do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents. Specifically, the species do not share a structural feature that would render them art-recognized equivalents.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 are pending.

Claims 2-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1 and 8-13 have been examined on the merits.

Claim Objections

Claim 12 is objected to because of the following informalities: The phrase "orally administration" should be replaced with "oral administration". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Oh et al (US 2002/0086838).

Amended claim 1 is now drawn to an agent for promoting osteogenesis and/or inhibiting bone resorption, comprising an active ingredient selected from a group (Applicant has elected plasminogen).

Claim 10 includes wherein the agent is in solid form.

Claim 12 includes wherein the agent is in a form for oral administration.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore as long as a reference describes an agent that contains the claimed active ingredient and is in a format suitable for the intended use as claimed by Applicant, the reference agent is deemed to anticipate the claimed agent.

Oh et al describe an agent comprising plasminogen that can be administered orally (page 3 para 27). Solid formulations are also disclosed (page 2 para 20).

While the intended use of the agent is different than that claimed by Applicant, the reference agent contains plasminogen and is in a format suitable for the claimed use and therefore anticipates Applicant's invention as claimed.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Motizuki et al (EP 0638314 A1).

Claim 13 includes wherein the active ingredient is obtained from one of milk or blood.

Motizuki et al describe an agent comprising plasminogen as a drug, wherein the plasminogen is derived from human plasma (blood) (page 2 lines 9-20).

While the intended use of the agent is different than that claimed by Applicant, the reference agent contains plasminogen and is in a format suitable for the claimed use and therefore anticipates Applicant's invention as claimed.

Claims 1, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bejanin et al (US 2003/0157485).

Claim 11 includes wherein the agent is in tablet form.

Bejanin et al describe a therapeutic agent that comprises plasminogen (page 107, para 985-page 108, para 986). The pharmaceutical compositions are taught to be in oral and tablet form (page 174 para 1605-1606).

While the intended use of the agent is different than that claimed by Applicant, the reference agent contains plasminogen and is in a format suitable for the claimed use and therefore anticipates Applicant's invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bejanin et al (US 2003/0157485) as applied to claims 1, 10-12 above, and further in view of Gillispie et al (US 2002/0150555) .

Claim 8 includes wherein the agent further comprises calcium preparations selected from the group consisting of calcium chloride, calcium carbonate, calcium lactate, and calcium from egg shells or milk and combinations thereof.

Claim 9 further includes ingredients selected from the group consisting of hydrated crystalline glucose, sugar ester, flavor and combinations thereof.

Bejanin et al describe a therapeutic agent that comprises plasminogen (page 107, para 985-page 108, para 986). The pharmaceutical compositions are taught to be in oral and tablet form (page 174 para 1605-1606). Physiologically acceptable carriers

are taught to include physiologically acceptable salts such as salts formed with calcium (page 173 para 1601-1603).

Bejanin et al does not specifically include calcium chloride, calcium carbonate, calcium lactate, and calcium from egg shells or milk.

Gillispie et al teach calcium salts that are suitable as carriers for pharmaceuticals include calcium lactate and calcium chloride (page 3 para 20).

Therefore, one of ordinary skill in the art would have been motivated to include calcium chloride or calcium lactate in the plasminogen composition of Bejanin et al because Gillispie et al teach that these calcium salts are suitable for addition as pharmaceutical carriers. One of ordinary skill in the art would have had a reasonable expectation of success because Benjanin et al teaches that calcium salts may be include in the pharmaceutical compositions as carriers and both references are teaching pharmaceutical preparations formulated for oral administration.

One of ordinary skill in the art would have been motivated to include a flavor or a sugar ester in the plasminogen composition of Benjanin et al because it would have made the oral formulations more appealing for administration. One of ordinary skill in the art would have had a reasonable expectation of success because Benjanin et al specifically teaches that excipients and auxiliaries that are commonly used in pharmaceuticals made be added (page 174 para 1605).

While the intended use of the reference agent is different than that claimed by Applicant, the reference agent contains plasminogen and is in a format suitable for the claimed use.

Therefore, the combined teachings of Benjanin et al and Gillispie et al render obvious Applicant's invention as claimed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bejanin et al (US 2003/0157485) as applied to claims 1, 10-12 above, and further in view of Motizuki et al (EP 0638314 A1).

Bejanin et al describe a therapeutic agent that comprises plasminogen (page 107, para 985-page 108, para 986). While the preferred source of plasminogen is taught to be liver cell extract (page 107 para 985), any source is taught as acceptable (page 108 para 986).

Benjanin et al do not specifically teach obtaining the plasminogen from milk or blood.

Motizuki et al describe an agent comprising plasminogen as a drug, wherein the plasminogen is derived from human plasma (blood) (page 2 lines 9-20).

Therefore, one of ordinary skill in the art would have been motivated to obtain the plasminogen from a blood source because Motizuki et al teach that this is a suitable source of plasminogen for therapeutic use. One of ordinary skill in the art would have had a reasonable expectation of success because Bejanin et al teach that any source may be used for the purification of the protein plasminogen and both references are preparing plasminogen for therapeutic use.

While the intended use of the reference agent is different than that claimed by Applicant, the reference agent contains plasminogen and is in a format suitable for the claimed use.

Therefore, the combined teachings of Benjanin et al and Motizuki et al render obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651

Laura Schuberg